

11 September 2015

Decision to list multivitamin for renal patients

PHARMAC is pleased to announce the approval of an agreement with Natural Health Laboratories Limited (a subsidiary of Douglas Pharmaceuticals) to fund a renal multivitamin (Clinicians Renal Vit).

This was the subject of a consultation letter dated 7 August 2015, available on PHARMAC's website at:

<http://www.pharmac.health.nz/news/consultation-2015-08-07-renal-multivitamin/>.

The proposal was approved as consulted on. In summary, the effect of the decision is that:

- Clinicians Renal Vit will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 October 2015. Funding is restricted to patients with chronic kidney disease (CKD) who are on dialysis or with CKD Grade 5.
- Pricing will be added to the existing listing in Part II of Section H for a multivitamin and mineral supplement, which is restricted to patients with burns and other criteria.

Details of the decision

From 1 October 2015:

In relation to Clinicians Renal Vit

- Clinicians Renal Vit will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following price and subsidy (ex-manufacturer, exclusive of GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Multivitamin renal	capsule	Clinicians Renal Vit	30	\$8.39

- Prior to 30 September 2017, the price of Clinicians Renal Vit would reduce if a volume based sale cap is exceeded.
- From 1 October 2017 the price of Clinicians Renal Vit will reduce to \$6.49 per 30 capsules.
- Clinicians Renal Vit capsules will be listed with all-at-once (STAT) dispensing.
- Clinicians Renal Vit capsules are protected from subsidy reduction or delisting until 1 October 2018.
- Clinicians Renal Vit will be listed subject to the following Special Authority criteria in the community and restrictions in the Hospital Medicines List:

Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1. The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis; or
2. The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <15 ml/min/1.73m² body surface area (BSA).

Hospital Medicines List restriction

Restricted

Either:

1. The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis; or
2. The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <15 ml/min/1.73m² body surface area (BSA).

In relation to Multivitamin and Mineral Boost capsules

- The existing listing for multivitamin and mineral supplement capsules in Part II of Section H of the Pharmaceutical Schedule will be amended to list Clinicians Multivitamin and Mineral Boost capsules at the following price (ex-manufacturer, exclusive of GST):

Chemical	Presentation	Brand	Pack size	Price
Multivitamin and mineral supplement	capsule	Clinicians Multivitamin and Mineral Boost	180	\$23.35

- The hospital restrictions for multivitamin and mineral supplement capsules remain the same, except for the removal of the note (as outlined below, deletions in strikethrough):

Restricted

Limited to 3 months treatment

Both:

1. Patient was admitted to hospital with burns; and
2. Any of the following:
 - 2.1 Burn size is greater than 15% of total body surface area (BSA) for all types of burns; or
 - 2.2 Burn size is greater than 10% of BSA for mid-dermal or deep dermal burns; or
 - 2.3 Nutritional status prior to admission or dietary intake is poor.

~~Note: Multivitamin and mineral supplement capsule composition includes vitamin A 250 IU, thiamine 2.5 mg, riboflavin 2.5 mg, nicotinamide 12.5 mg, vitamin B5 10 mg, pyridoxine 5 mg, vitamin B12 6.2 mcg, vitamin C 125 mg, cholecalciferol 2.5 mcg, vitamin E 25 mg, betaine 12.5 mg, biotin 12.5 mcg, boron 250 mcg, calcium 25 mg, choline 6.2 mg, chromium 25 mcg, citric acid 50 mg, citrus bioflavonoid complex 50 mg, co-enzyme Q10 1.2 mg, copper 125 mcg, folic acid 37.5 mcg, inositol 6.2 mg, iodine 25 mcg, iron 250 mcg, L-Glutamine 6.2 mg, magnesium 12.5 mg, molybdenum 12.5 mcg, manganese 0.5 mg, potassium 5 mg, selenium 18.7 mcg, zinc 1.9 mg~~

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 21 August 2015 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of

the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
<p>Request to include Clinicians Renal Vit on schedule of agents that renal dietitians can prescribe and that dietitians have the ability to apply for Special Authority for Clinicians Renal Vit.</p>	<p>PHARMAC recently consulted on a proposal to remove rule 3.5 of Section A of the Pharmaceutical Schedule - a rule that currently limits subsidies being paid on dietitians' prescription to a specified list of products. A decision is expected on this proposal later this month. The consultation letter dated 4 August 2015 is available on PHARMAC's website at: http://www.pharmac.health.nz/news/consultation-2015-08-04-dietitian-prescribers/</p> <p>If this proposal is approved, Clinicians Renal Vit could be prescribed by dietitians if it is determined to be within their scope of practice by the Dietitians Board and it would be fully funded.</p> <p>The Special Authority is limited to any relevant practitioner which would include dietitians.</p>
<p>Patients on dialysis and CKD Stage 5 are high priority, however would also like it made available to patients with CKD Stage 4. Request PHARMAC considers this in the future.</p>	<p>PHARMAC considers the target patient population of those on dialysis or CKD Stage 5 is appropriate and aligns with that identified by PTAC and renal clinicians as having the greatest need. We estimate there would be at least 8500 patients in New Zealand with CKD Stage 4 and including this group would significantly increase the budget impact of this proposal.</p> <p>The Special Authority criteria remain as consulted on. We note widening access to patients with CKD Stage 4 could be considered in the future.</p>
<p>Clinicians Renal Vit would be appropriate to use in teenagers on dialysis. This patient group needs optimal nutrition to maximise growth potential.</p>	<p>Adolescent patients on dialysis would meet the Special Authority criteria for multivitamin renal.</p>
<p>Clinicians Renal Vit has been carefully formulated to replace vitamins commonly deficient in dialysis patients and would potentially replace existing vitamin supplements, reducing pill burden for patients.</p>	<p>Noted.</p>
<p>Support the availability of renal specific vitamin - many renal patients lack variety in their diets, have increase vitamin and trace mineral losses through dialysis, and have high rates of malnutrition. Patients would benefit from this product without the risk of vitamin A toxicity.</p>	<p>Noted.</p>

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz.